IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Elizabeth MOYER, et al.	Group Art Unit: 1645
Serial Number: 09/393,590	Examiner: Sarvamangala J. N. Devi
Filing Date: September 9, 1999	**CONFIRMATION NO: 2967**
Title: STABLE LIQUID FORMULATIONS OF BOTULINUM TOXIN	

ELECTRONICALLY FILED ON: April 25 , 2006

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

A. ☐ *37 CFR §1.97(b).* This Information Disclosure Statement should be considered by the Office because:

☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);

-- OR --

☐ (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;

-- OR --

☐ (3) It is being filed before the mailing of a first Office action on the merits;

-- OR --

☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.

B. ☐ *37 CFR §1.97(c).* Although this Information Disclosure Statement is being filed after the period specified in *37 CFR §1.97(b),* above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

☐ a statement as specified in §1.97(e) provided concurrently herewith;

-- OR --

☐ a fee of $180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

C. ☒ *37 CFR §1.97(d).* Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

i. a statement as specified in §1.97(e);

-- AND --

ii. a fee of $180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

D. ☒ *37 CFR §1.97(e).* Statement.

☐ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(c);

-- AND/OR --

☒ A statement is provided herewith to satisfy the requirement under 37 CFR §§1.97(d);

-- AND/OR --

☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under 37 C.F.R. § 1.97(e)(1) as provided for under MPEP 609.04(b) V.

E. ☐ *Statement Under 37 C.F.R. §1.704(d).* Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ *37 CFR §1.98(a)(2).* The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☐ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

G. ☒ *37 CFR §1.98(a)(3).* The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☒ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

Roche Lexikon Medizin 5. Augage is in the German language. An English translation is provided.

H. ☐ *37 CFR §1.98(d).* Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

I. ☒ *Fee Authorization*. The Commissioner is hereby authorized to charge the above-referenced fees of $180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.31242-701.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: April 25, 2006

By: _____
Albert P. Halluin, Reg. No. 25,227

650 Page Mill Road
Palo Alto, CA 94304-1050
(650) 493-9300
Customer No. 021971

STATEMENTS UNDER 37 C.F.R. § 1.97(E)

(Attachment to Information Disclosure Statement)

☐ *37 CFR §1.97(e)(1).* **THE UNDERSIGNED HEREBY STATES THAT** each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement:

☐ All references cited herein;

-- OR --

☐ The following subset of references: _____

--AND/OR--

☒ *37 CFR §1.97(e)(2).* **THE UNDERSIGNED HEREBY STATES THAT** no item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement:

☒ All references cited herein;

-- OR --

☐ The following subset of references: _____

Respectfully submitted,

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PTO/SB/08 (07/05)
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Substitute for form 1449/PTO **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** *(Use as many sheets as necessary)*				***Complete if Known***	
				Application Number	09/393,590
				Filing Date	September 9, 1999
				First Named Inventor	Elizabeth Moyer
				Art Unit	1645
				Examiner Name	Sarvamangala J. N. Devi
Sheet	1	Of	4	Attorney Docket Number	31242-701.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
		Appeal Brief dated April 3, 2006 to Technical Board of Appeal for European Patent No. 99 94 5649.4.	
		Roche Lexikon Medizin 5. Augage (in German with English translation)	√
		SHONE, et al. Monoclonal antibody-based immunoassay for type A Clostridium botulinum toxin is comparable to the mouse bioassay. Appl. Environ. Microbiol. 1985; 50(1):63-67.	
		EUTICK, Malvin L. Statutory Declaration dated March 23, 2006 for Australian Patent Application No. 58214/99 in the name of Solstice Neurosciences, Inc., entitled "Stable liquid formulations of Botulinum Toxin" and in the matter of opposition thereto by Allergan, Inc.	
		EXHIBIT ME-1 (Resume of Malvin L. Eutick) referred to in the Statutory Declaration of Malvin L. Eutick dated March 23, 2006.	
		EXHIBIT ME-2 (Facts arguments presented in support of the opposition against European patent No. 1 112 082) referred to in the Statutory Declaration of Malvin L. Eutick dated March 23, 2006.	
		EXHIBIT ME-3 (SHONE, et al. Monoclonal antibody-based immunoassay for type A Clostridium botulinum toxin is comparable to the mouse bioassay. Appl. Environ. Microbiol. 1985; 50(1):63-67.) referred to in the Statutory Declaration of Malvin L. Eutick dated March 23, 2006.	

Examiner Signature		Date Considered	

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		HALLIS, et al. Development of novel assays for botulinum type A and B neurotoxins based on their endopeptidase activities. J. Clin. Microbiol. 1996; 34(8):1934-1938.	
		MARSHALL, Philip Andrew. Statutory Declaration dated March 8, 2006 for Australian Patent Application No. 58214/99 in the name of Solstice Neurosciences, Inc., entitled "Stable liquid formulations of Botulinum Toxin" and in the matter of opposition thereto by Allergan, Inc. (33 pages)	
		MARSHALL, Philip Andrew. Statutory Declaration dated March 8, 2006 for Australian Patent Application No. 58214/99 in the name of Solstice Neurosciences, Inc., entitled "Stable liquid formulations of Botulinum Toxin" and in the matter of opposition thereto by Allergan, Inc. (8 pages)	
		EXHIBIT PM-1 (Resume of Philip Andrew Marshall) referred to in the Statutory Declaration of Philip Marshall dated March 8, 2006.	
		EXHIBIT PM-2 (Modern Pharmaceutics by Banker, et al.) referred to in the Statutory Declaration of Philip Marshall dated March 8, 2006.	
		EXHIBIT PM-3 (Stability of Protein Pharmaceuticals by Ahern, et al.) referred to in the Statutory Declaration of Philip Marshall dated March 8, 2006.	
		EXHIBIT PM-4 (HEXSEL, et al. Comment on Multicenter, double-blind study of the efficacy of injections with botulinum toxin type A reconstituted up to six consecutive weeks before application. Dermatol. Surg. 2004; 30(5):823.) referred to in the Statutory Declaration of Philip Marshall dated March 8, 2006.	
		EXHIBIT PM-4 (MA, et al. Efficacy of reconstituted and stored botulinum toxin type A: an electrophysiologic and visual study in the auricular muscle of the rabbit. Plast. Reconstr. Surg. 2003;111(7):2419-26; discussion 2427-31 (Abstract)) referred to in the Statutory Declaration of Philip Marshall dated March 8, 2006.	

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		EXHIBIT PM-4 (ALAM, et al. Pain associated with injection of botulinum A exotoxin reconstituted using isotonic sodium chloride with and without preservative: a double-blind, randomized controlled trial. Arch. Dermatol. 2002; 138(4):510-4 (Abstract)) referred to in the Statutory Declaration of Philip Marshall dated March 8, 2006.	
		EXHIBIT PM-4 (KLEIN, A. W. Dilution and storage of botulinum toxin. Dermatol. Surg. 1998; 24(11):1179-80 (Abstract)) referred to in the Statutory Declaration of Philip Marshall dated March 8, 2006.	
		EXHIBIT PM-4 (SLOOP, et al. Reconstituted botulinum toxin type A does not lose potency in humans if it is refrozen or refrigerated for 2 weeks before use. Neurology. 1997; 48(1):249-53 (Abstract)) referred to in the Statutory Declaration of Philip Marshall dated March 8, 2006.	
		EXHIBIT PM-4 (MCLELLAN, et al. Therapeutic botulinum type A toxin: factors affecting potency. Toxicon. 1996; 34(9):975-85 (Abstract)) referred to in the Statutory Declaration of Philip Marshall dated March 8, 2006.	
		EXHIBIT PM-4 (GARTLAN, et al. Crystalline preparation of botulinum toxin type A (Botox): degradation in potency with storage. Otolaryngol. Head Neck Surg. 1993; 108(2):135-40 (Abstract)) referred to in the Statutory Declaration of Philip Marshall dated March 8, 2006.	
		EXHIBIT PM-5 (COFFIELD, et al. The site and mechanism of action of botulinum neurotoxin. In: *Therapy With Botulinum Toxin*. Edited by J. Jankovic and M. Hallett. New York. Marcel Dekker. 1994; p. 3-13.) referred to in the Statutory Declaration of Philip Marshall dated March 8, 2006.	
		EXHIBIT PM-5 (DASGUPTA, B. R. Structures of Botulinum Neurotoxin, Its Functional Domains, and Perspectives on the Crystalline Type A Toxin. In: *Therapy With Botulinum Toxin*. Edited by J. Jankovic and M. Hallett. New York: Marcel Dekker. 1994; p. 15-39.) referred to in the Statutory Declaration of Philip Marshall dated March 8, 2006.	

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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		Annexure EM-1 (Resume of Elizabeth D. Moyer) referred to in the Statutory Declaration of Elizabeth D. Moyer dated April 14, 2006.	
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